510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: k040848

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the VIP International Wholesalers, Corp., EZ Smart Blood Glucose Monitoring System.

C. Analyte: Glucose

D. Type of Test: Quantitative electrochemical biosensor**.**

E. Applicant: VIP International Wholesalers. Corp.

F. Proprietary and Established Names: EZ Smart Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section: 21 CFR §862.1345, Glucose test system.
2. Classification: Class II
3. Product Code: NBW, CGA
4. Panel: 75

H. Intended Use:

1. Intended use(s):

   The EZ Smart Blood Glucose Test Strips are used with the EZ Smart Blood Glucose Meter to measure glucose (sugar) in whole blood. The EZ Smart Test Strips are for testing outside the body (in vitro diagnostic use). The EZ Smart Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels for better glucose level control among diabetics.

2. Indication(s) for use:

   The EZ Smart Blood Glucose Test Strips are used with the EZ Smart Blood Glucose Meter to measure glucose (sugar) in whole blood. The EZ Smart Test Strips are for testing outside the body (in vitro diagnostic use). The EZ Smart Blood Glucose Monitoring System is intended for use in the home and in

professional settings to monitor blood glucose levels for better glucose level control among diabetics.

3. Special condition for use statement(s):

EZ Smart Blood Glucose Test Strips and EZ Smart Control Solutions are to be used only with the EZ Smart Blood Glucose Meter to test glucose in fresh capillary whole blood only. This meter is not to be used for Alternate Site Testing or Neonatal Testing.

4. Special instrument Requirements:

EZ Smart Blood Glucose Meter.

I. Device Description:

The EZ Smart Blood Glucose Test Strips are used with the EZ Smart Blood Glucose Meter to quantitatively measure glucose in capillary whole blood. When the edge of the EZ Smart test strip is touched to a drop of blood, the test strip draws the blood into the sample chamber and your glucose reading is displayed on the meter after 10 seconds. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3 mmol/L). The EZ Smart Test Strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer Elite with the Elite Test Strips

2. Predicate K number(s): k964630 (Bayer Elite)
   k992342 (Bayer Elite Test Strips)

3. Comparison with Predicate:

The VIP International Wholesalers, Corp., EZ Smart Blood Glucose Monitoring System is equivalent to the Bayer Elite Blood Glucose Monitoring System previously cleared under (K964630). The table below lists the similarities and differences between the Predicate and Proposed device.

Substantial Equivalence Comparison

Similarities

Item	Predicate Device Bayer ELITE (K964630)	Proposed Device EZ Smart
Similarities	1. Monitors glucose using whole blood.	1. Monitors glucose using whole blood.

	2. Directly displays results without requiring calculation. 3. Test principle includes measuring a current produced by a chemical reaction. 4. Test principle: Uses glucose oxidase reaction. 5. Measuring range: 20 to 600 ng/dL.	2. Directly displays results without requiring calculation. 3. Test principle includes measuring a current produced by a chemical reaction. 4. Test principle: Uses glucose oxidase reaction. 5. Measuring range: 20 to 600 mg/dL.

Differences

Item	**Predicate Device Bayer ELITE (K964630)**	**Proposed Device EZ Smart**
Differences	1. Size: 97.8 x 56 x 14.5 mm. 2. Measuring time: 30 seconds.	1. Size: 94 x 49 x 17 mm. 2. Measuring time: 10 seconds.

K. Standard/Guidance Document Referenced (if applicable):

The EZ Smart Blood Glucose Monitoring System has been tested with the listed standards and found in compliance with the council EMC directive 89/336/EEC. It is possible to use CE markings to demonstrate the compliance with this EMC Directive.

Test Standards		
EN 60601-1-2/1993	Medical electrical equipment – Electromagnetic compatibility	
	EN 55011/1998 + A1/1999	Emissions, Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and media (ISM) radio-frequency equipment.
	IEC 801-3/1984	Immunity, Electrostatic discharge
	IEC 801-3/1984 ENV 50204/1995	Immunity, Radio-frequency electromagnetic field.

CDRH document, Write it Right, Recommendations for Developing User Instruction Manuals for Medical Devices Used in House Health Care.

NCCLS Guideline Gp-14P, Labeling for Home Use In Vitro Testing Products, (SMOG)
NCCLS Guideline EP6-A.

L. Test Principle:

The test principle is based on electrochemical biosensor technology using glucose oxidase. The strip uses the enzyme glucose oxidase to produce a current that will stimulate a chemical reaction. This reaction is measured by the meter and displayed as the blood glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

The following precision studies were obtained from spiked venous blood specimens and control solution in the R&D laboratories at the manufacturer's site. This precision study is a measurement of strip-to-strip (within-run) reproducibility by calculating the mean, standard deviation, and coefficient of variation for test conducted on strips from three different lots (between-run). Whole blood samples from volunteers were collected with EDTA Vacutainer® tubes and spiked with β-D-Glucose to desired glucose concentrations. The spikes samples were gently mixed by inverting 20 times. The desired glucose concentrations used ranges at 5 different levels; low concentration (~30-50 mg/dL) normal concentration (~ 51-110 mg/dL), high normal (~ 111-150 mg/dL), mid high (~ 151-250 mg/dL), and high concentration (~ 251-400 mg/dL).

A YSI 2300 glucose analyzer (Yellow Springs Instrument, Yellow Springs, Ohio, USA) was used to measure the glucose concentration in venous samples. This YSI 2300 glucose analyzer was used throughout the study as the "gold standard". All measurements were done in "Normal Mode" and a calibration mode of "5/15" (calibrating every 5 measurements or every 15 minutes).

Results presented in the table below are the results of the precision study conducted using the EZ Smart meters.

Glucose Level (mg/dL)	44.9	89.8	131	224	361
Number of Tests	30	30	30	30	30
Average (mg/dL)	49.7	85.0	121.4	221.0	362.1
S.D. (mg/dL)	2.1	1.6	4.0	6.8	9.0
C.V. (%)	4.2%	1.8%	3.3%	3.1%	2.5%

Regression (y) = 1.003x-2.46
$r_2 = 0.9981$

The results obtained from test conducted on strips from three different lots (between-run) are presented below:

Lot No.	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV%
Meter Serial # 1 M020242	44.9	49.20	1.32	2.68
	89.8	80.60	2.67	3.32
	131	122.30	5.19	4.24
	224	215.70	7.02	3.26
	361	357.80	4.18	1.17
Meter Serial # 2 M0202426	44.9	49.70	2.11	4.25
	89.8	85.00	1.56	1.84
	131	121.40	3.68	3.28
	224	221.00	6.80	3.08
	361	362.10	9.02	2.49
Meter Serial # 3 M0202426	44.9	49.90	1.73	3.46
	89.8	82.60	2.41	2.92
	131	118.20	6.32	5.35
	224	227.60	7.00	3.07
	361	357.30	6.33	1.77

b. Linearity/assay reportable range:

Linearity (analytical range) studies were designed in accordance with NCCLS Guideline EP6-A. Venous blood was drawn from healthy volunteers and collected into lithium heparin vacutainer® tubes. The blood was then placed in a room temperature environment overnight, until glycolysis took place to reduce the glucose concentration to nearly zero. The blood was then pooled and allocated to lithium heparin tubes. A small amount of high concentration glucose (10,000 mg/dL) was added to each tube to obtain the desired blood glucose levels needed to perform the test.

Recovery tests were performed by confirming the blood glucose concentration with the YSI 2300. Blood samples with glucose concentrations ranging from 20 to 600 mg/dL were then tested with the EZ Smart Blood Glucose Monitoring System. Three lots of EZ Smart Test Strips, Chosen at random, were used during the test. The test results were evaluated to describe accuracy over the entire range of blood glucose values. A linear regression analysis was performed by the method of least squares ($Y = 0.9717X + 3.66$, $R^2 = 0.9987$). The sensitivity of the system was determined by the slope of the regression line whereas the linearity was determined by the correlation coefficient of the regression line.

All measurements determined by the EZ Smart System are within a 15% bias of the reference (YSI 2300) results (glucose concentration > 100 mg/dL) and a 15 mg/dL bias of the reference (YSI 2300) results (glucose concentration < 100 mg/dL) see table below:

The sensitivity of EZ Smart Blood Glucose Monitoring System

YSI (mg/dL)	**20**	**75**	**152**	**258**	**359**	**482**	**600**
EZ Smart Results **Lot R030212**	25	77	148	269	358	478	595
	23	82	139	258	354	459	589
	24	77	158	254	368	486	570
	20	71	156	245	348	469	591
	21	74	147	249	347	465	600
	28	76	155	243	345	462	597
	30	83	148	255	350	471	582
	26	76	155	248	351	467	591
MEAN	24.63	77.00	150.75	252.63	352.63	469.63	589.38
SD	3.38	3.93	6.36	8.37	7.44	8.78	9.55
CV%	13.72%	5.10%	4.22%	3.31%	2.11%	1.87%	1.62%
Bias%	23.13%	2.67%	-0.82%	-2.08%	-1.78%	-2.57%	-1.77%

c. Traceability (controls, calibrators, or method):

Traceability has been reference by the manufacturer to ISO 17511.

d. Detection limit:

The detection range is from 20 – 600 mg/dL (1.1 to 33.3 mmol/L). See linearity/assay detection limit above.

e. Analytical specificity:

Interference testing was conducted to determine the effect of select endogenous and exogenous substances. The following study was used to elucidate whether the EZ Smart blood glucose Monitoring System is capable of a precise reading in blood samples containing the interferences. Interference studies were conducted according to NCCLS EP7-P.

The Interfering Effect of Drugs and Chemical Compounds on EZ Smart Test Strips.

Interfering Compounds	Physiological Levels Test Conc.	Test Concentration	No Interference Level of EZ Smart Test Strip
Acetone		6 mg/ml	6 mg/ml
Acetaminophen	20 µg/ml	40 µg/ml	30µg/ml
Ascorbic Acid	12 µg/ml	150 µg/ml	75 µg/ml
Alcohol		35 µg/ml	35 mg/ml
Barbital		1 mg/ml	1 mg/ml
Benzoic Acid		14.4 mg/ml	14.4 mg/ml
Bilirubin		200 µg/ml	200 µg/ml

Caffeine		1 mg/ml	1 mg/ml
Cholesterol	3 mg/ml	5 mg/ml	5 mg/ml
Cholic Acid		6 µg/ml	6 µmol/L
Creatinine	15 µg/ml	300 µg/ml	300 µg/ml
EDTA		4 mg/ml	4 mg/ml
Ephedrine	0.1 µg/ml	100 µg/ml	100µg/ml
Ethylene Glycol		40 µg/ml	40 mg/ml
Erythromycin		2 mg/ml	2 mg/ml
Glycerol		1 mmol/L	1 mmol/L
Ibuprofen	42 µg/ml	400 µg/ml	400µg/ml
L-DOPA	3 µg/ml	20 µg/ml	10 µg/ml
Lecithin		50 µg/ml	50 mg/ml
Potassium Chloride		10 µg/ml	10 mmol/L
Salicylate	0.3 mg/ml	1.25 mg/ml	1.25 mg/ml
Sodium Bicarbonate		40 mmol/L	30 mmol/L
Sodium Fluoride		5 mg/ml	3.75 mg/ml
Tetracycline	4 µg/ml	40 µg/ml	40 µg/ml
Tolazamide	25 µg/ml	50 µg/ml	37.5 mg/ml
Tolbutamide	0.1 mg/ml	1 mg/ml	1 mg/ml
Triglyceride	1.9 mg/ml	30 mg/ml	22.5 mg/ml

f. Assay cut-off: NA

2. Comparison studies:

a. Method comparison with predicate device:

203 patients were enrolled in an OTC study that used the Bayer Elite as the predicate device and the YSI model 2300 as the reference method. VIP International instituted the clinical trials at three different locations in the continental United States. The patients performed their own fingerstick and ran the test unassisted with the EZ Smart meter. The results were recorded on the questionnaire form provided. The patient then performed their own test with the Bayer Elite meter using blood from the original fingerstick and recorded the results. A technician collected a blood sample from the patient when possible for analysis on the YSI Model 2300 comparative laboratory method. The results obtained by the patients on the EZ Smart Glucometer, Bayer Elite Glucometer, and by the technical staff on the YSI using the capillary blood are presented in the chart below. Using capillary blood, 184/202 or 91.1% of the results were within 20% of the YSI values.

Site #	**N**	**X-Method Capillary**	**Y-Method Capillary**	**R**	**Regular Slope**	**Regular Intercept**	**Deming Slope**	**Deming Intercept**
#1	38	YSI-Ref	EZ Smart	0.9574	1.023	2.7	1.072	-5.1
#2	87	YSI	EZ Smart	0.9768	0.9338	1.7	0.9550	-1.2
#3	77	YSI	EZ Smart	0.9654	0.9446	0.6	0.9776	-4.7

#1	38	Bayer Elite	EZ Smart	0.9676	0.8651	15.6	0.8907	11.1
#2	87	Bayer Elite	EZ Smart	0.9835	0.8890	11.4	0.9023	9.7
#3	77	Bayer Elite	EZ Smart	0.9789	0.8557	10.7	0.8716	8.0
All	202	YSI	EZ Smart	0.9644	0.9678	-0.1	1.004	-5.5
All	202	Bayer Elite	EZ Smart	0.9815	0.8778	10.6	0.8925	8.4
All	202	YSI	Bayer Elite	0.9637				

b. Matrix comparison: *NA*

3. Clinical studies:
   a. Clinical sensitivity: *NA*

   b. Clinical specificity: *NA*

   c. Other clinical supportive data (when a and b is not applicable): NA

4. Clinical cut-off: NA

5. Expected values/Reference range:

The normal fasting glucose range for a non-diabetic adult is 70 to 110 mg/dL. (3.9 to 6.1 mmol/L)[1]. One to two hours after meals, normal glucose values should be less than 120 mg/dL (6.7 mm0l/L)[2].

1. Burtis CA Ashwood ER, eds: Tietz Textbook of Clinical Chemistry. 2nd Edition. W.B. Saunders. Philadelphia. 1994. p. 2190.

2. Krall LP and Beaser RS: Joslin Diabetes Manual. Lea and Febiger. Philadelphia 1989. p. 138.

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision